

K962486

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

DEC 27 1996

NAME OF FIRM: DePuy Inc.
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Warsaw, IN 46581-0988

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TRADE NAME: DePuy Motech PEAK™ Anterior Compression Plate System

COMMON NAME: Anterior Cervical Plate

CLASSIFICATION: 888.3060: Spinal intervertebral body fixation orthosis

PRODUCT CODE: 87 KWQ

**SUBSTANTIALLY
EQUIVALENT DEVICES:** Acromed AcroPlate Anterior Cervical System
Codman Anterior Cervical Plate System
Aesculap Caspar Cervical Plate

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Motech PEAK™ Anterior Compression Plate System consists of 12 different Ti-6Al-4V plates. The plates are available in 4 design segments (1, 2, 3 or 4 "I" shaped segments), each being available in 3 lengths. The system also includes Ti-6Al-4V 3.5mm cortical and 4.0mm cancellous screws in 13 lengths.

The DePuy Motech PEAK™ Anterior Compression Plate System is intended for use in the treatment of anterior cervical spine instability as a result of fractures, dislocations, subluxations, tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylosis or a previously failed cervical surgery.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Motech PEAK™ Anterior Compression Plate System is similar in material, design and intended use to the Acromed AcroPlate Anterior Cervical System, the Codman Anterior Cervical Plate System and the Aesculap Cervical Plate System. All of these systems consist of Ti-6Al-4V or CP Titanium bone plates and screws intended for anterior stabilization of the cervical spine. Mechanical testing indicates that the fatigue strength of the DePuy Motech PEAK™ Anterior Compression Plate is similar to that of the Acromed AcroPlate and is adequate for its intended use.